

DETAILED ACTION

Acknowledgement of Receipt/Status of Claims

This Office Action is in response to the amendment filed December 2, 2011. Claims 2,4-7,9-13 and 15-17 are pending in the application. Claims 1,3,8 and 14 have been cancelled. Claims 2,4-7,9-11 and 13 have been amended. Claims 16 and 17 are newly added. Claims 9 and 11 have been withdrawn as being directed to a non-elected invention. Claims **2,4-7,10,12,13 and 15-17** are being examined for patentability.

Maintained Rejections

Applicant's arguments filed December 2, 2011 are acknowledged and have been fully considered.

The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application. The rejection of claims 2,4-7,10,12,13 and 15 under 35 U.S.C. 103(a) as being unpatentable over Karl et al. (US Patent Application 2005/0132500A1) and/or Skovmand (WO 01/37662 A1) **is maintained** for the reasons of record. Applicants' cancellation of claims 1,3,8 and 14 renders their rejections moot.

Claim Rejections - 35 USC § 103

Art Unit: 1617

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2,4-7,10,12,13 and 15 *remain* rejected and claims 16-17 are *newly* rejected under 35 U.S.C. 103(a) as being unpatentable over Karl et al. (US Patent Application 2005/0132500A1, previously cited) and/or Skovmand (WO 01/37662 A1, previously cited).

Applicant's Invention

Applicant is claiming an insecticide composition comprising a non-pyrethroid insecticide in combination with an insect repellent, wherein:
the non-pyrethroid insecticide is selected from the group consisting of: carbamate insecticide and organophosphate insecticide, and the insect repellent is selected from the group consisting of: of N,N-diethyl-meta-toluamide (DEET) and 2-(2- hydroxy-ethyl)-piperidine carboxylic acid ester of 1-methyl- propyl (KBR2023), a concentration of the non-pyrethroid insecticide in the composition is lower than a lethal concentration i00 (LCI00) when the insecticide is used alone, and a concentration of the insect repellent in the insecticide composition is lower than the concentration of insect repellent procuring a protective effect when the insect repellent is used alone.

**Determination of the scope and the content of the prior art
(MPEP 2141.01)**

Karl et al. teach an insecticide composition for application to a textile material or plastic material wherein the composition comprises a mixture of at least one insecticide and/or at least one repellent (claim 1 of Karl et al.). The insecticide is selected from organophosphorous compounds such as pirimiphos-ethyl and piriphos-methyl (claim 4 of Karl et al., elected insecticide and limitation of instant claims **2 ,7,16 and 17**) and the repellent is selected from compounds such as N,N-Diethyl-meta-toluamine (i.e., DEET, claim 4 of Karl et al. and elected repellent and limitation of instant claims **10 and 17**). The composition comprises from about 0.001 to 95% by weight of the insecticide and/or repellent (claim 7 of Karl et al., limitation of instant claim **6**). Karl et al. teach impregnated textile material and a process for the impregnation of textile material which may be in the form of garments such as socks, trousers, shirts, etc. and nettings which are used for mosquito nets or covering (see claims 13 and 14 of Karl et al. and [0068], limitation of instant claims **12 and 15**).

Skovmand teaches an impregnated netting or fabric for insect or tick and/or repellence of an insect or tick comprising an insecticide and/or a repellent wherein the insecticide is selected from organophosphorous compounds such as pirimiphos-ethyl and piriphos-methyl (claims 1 and 8 of Skovmand, elected insecticide and limitation of instant claim **12**) and the repellent is selected from compounds such as N,N-Diethyl-meta-toluamine (i.e., DEET, also claims 1 and 8 of Skovmand, elected repellent and limitation of instant claim **12**). Skovmand teaches a process for impregnation of a fabric or netting as well as a composition for impregnation of fabrics comprising the aforementioned insecticide/repellent combination wherein the composition comprises

Art Unit: 1617

from about 0.001 to 95% by weight of the insecticide and/or repellent (claims 18 and 9 of Skovmand, limitation of instant claims **1, 6-7,10 and 15**).

**Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)**

The difference between the invention of the instant application and that of Karl et al. and Skovmand is that Karl et al. and Skovmand do not expressly teach that the concentration of the insecticide in the product being lower (i.e., LC20 to LC40, and LC30) than its lethal concentration 100 (LC100), when it is used alone, and that the concentration of the insect repellent in the product being lower than the concentration of the insect repellent procuring a maximum repellent effect and a protective effect when it is used alone (limitation of instant claims **2 and 4-5**) .

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

The teachings of Karl et al. and Skovmand are directed to combinations of repellents and non- pyrethroid insecticides. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to combine the

Art Unit: 1617

teachings Karl et al. and Skovmand to arrive at products containing at least one non-pyrethroid insecticide and at least one insect repellent wherein the concentration of the insecticide in the product being lower (i.e., LC20 to LC40, and LC30) than its lethal concentration 100 (LC100), when it is used alone, and that the concentration of the insect repellent in the product being lower than the concentration of the insect repellent procuring a maximum repellent effect and a protective effect when it is used alone. It is known in the art that combining insecticidal actives increases the efficacy of an insecticide such that the maximum level of insects killed for a given application rate of an insecticide is increased, or alternatively, the application rate of an insecticide giving the maximum level of insects killed can be reduced. One would have been motivated to combine these references in order to receive the expected benefit of an increase in the efficacy of the claimed insecticide. Thus, one would have been motivated to make this combination in order to receive the expected benefit of having products impregnated with low doses of repellents and insecticides that will last longer due to the combination of the non-pyrethroid insecticide and the repellent.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of

ordinary skill in the art at the time the invention was made, as evidenced by the teachings of the cited references, especially in the absence of evidence to the contrary.

Examiner's Response to Applicant's Remarks

Applicant's arguments filed on December 2, 2011, with respect to the 103 rejection of claims 2,4-7,10,12,13 and 15 as being unpatentable over Karl et al. (US Patent Application 2005/0132500A1) and/or Skovmand (WO 01/37662 A1) have been fully considered but they are not persuasive. Applicant argues that the Office appears to rely on the general knowledge that combining insecticidal actives increases the efficacy of an insecticide such that the maximum level of insects killed for a given application rate of an insecticide is increased, or alternatively, the application rate of an insecticide giving the maximum level of insects killed can be reduced and that the Office contends that one would have been motivated to combine the KARL and SKOVMAND references with this general knowledge in order to obtain the expected benefit of an increase in the efficacy of the claimed insecticide and of having products impregnated with low doses of repellents and insecticide that will last longer due to the combination of the non-pyrethroid insecticide and the repellent. Applicants disagree with this conclusion and argue that "Insecticidal active" is a global term to designate two different classes of molecules, i.e., insecticides and repellents. According to the Oxford English Dictionary, Applicant argues that the definition of insecticide is "a substance used for

Art Unit: 1617

killing insects" whereas a repellent is "a substance able to repel a particular thing" (i.e., drive away mosquitoes in the present case). Thus, Applicant argues that by combining these two classes of molecules, one of ordinary skill expects two different effects on mosquitoes - driving away mosquitoes and killing those not sensitive to the repellent action. In its "Guidelines for the Control of Flies Closely Associated with Humans", Applicant argues that the World Health Organization gives suitable concentrations of insecticides for space treatment and that most of the compounds listed in this document are also used to impregnate nets to fight against mosquitoes. By way of example, Applicant argues that the World Health Organization recommended a dosage of permethrin in a combination mixture that includes permethrin is from 5 to 15 g/ha, whereas the recommended dosage of permethrin when used alone is from 5 to 10 g/ha. Applicant further argues that the recommended dosage of deltamethrin in a combination mixture that includes deltamethrin is from 0.5 to 1.0 g/ha, whereas the recommended dosage of deltamethrin when used alone is from 0.3 to 0.7 g/ha. Hence, Applicant concludes that it is general knowledge in the art that combining insecticidal actives does not necessarily allow reducing the application rate of an insecticide. However, the Examiner is not persuaded by Applicant's argument because Table 2 of the World Health Organization to which Applicant has previously discussed not only suggests a combination mixture that includes permethrin from 5 to 15 g/ha but also suggests a combination mixture that includes permethrin is from 5 to 7.5 g/ha when used in cold fog treatments which is a reduced application rate in comparison to 5 to 10 g/ha which is the recommended dosage of permethrin when used alone. Further, it seems that

Art Unit: 1617

Applicant has the numbers mixed for the recommended dosage of deltamethrin. Tables 2 of the World Health Organization recommends an application dosage of deltamethrin in a combination mixture that includes deltamethrin is actually from 0.3 to 0.7 g/ha in both cold and thermal fog formulations versus 0.5 to 1.0 g/ha which is the recommended dosage of deltamethrin when used alone as disclosed in Table 1 of the World Health Organization document presented by Applicant (see tables 1 and 2 of the World Health Organization submitted by Applicant on December 2, 2011). Thus, this document proves that it is, in fact, general knowledge in the art that combining insecticidal actives does necessarily allow reducing the application rate of an insecticide.

Next, Applicant argues that KARL et al. and SKOVMAND disclose compositions including at least one insecticide and/or one repellent and at least one binder and that both references list several different categories of insecticides (e.g., pyrethroid, carbamate and organophosphorous) and repellent. Applicant argues that one of ordinary skill in the art would have to choose among 36 non-pyrethroid insecticides (17 carbamate and 19 organophosphorous insecticides) and 18 repellents to determine any combination of insecticide and repellent such as that disclosed in the present application. Moreover, Applicant argues that these references fail to provide any direction to select specific mixture of compounds and to choose specific doses of each of the compounds. Furthermore, Applicant argues that each of the embodiments exemplified in the KARL et al. and SKOVMAND references concern pyrethroid

Art Unit: 1617

insecticides. Thus, Applicant concludes that one would have to choose between 648 different combinations of non-pyrethroid insecticides and repellents, and to try infinite possible choices of concentrations of these two compounds, in order to arrive at the claimed composition. Contrary to the position taken by the Office Action, Applicant argues that one of ordinary skill in the art, in view of the teachings of KARL et al. and SKOVMAND would not have expected any benefit of increased efficacy from the combination of insecticide and repellent in an insecticide composition as presently claimed. However, the Examiner is not persuaded by Applicant's argument because when considering a prior art's teaching, the whole reference is considered. According to MPEP 2123, "patents are relevant as prior art for all they contain":

2123 Rejection Over Prior Art's Broad Disclosure Instead of Preferred Embodiments [R-5]

I. PATENTS ARE RELEVANT AS PRIOR ART FOR ALL THEY CONTAIN

"The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)).

A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989). See also *Upsher-Smith Labs. v. Pamlab, LLC*, 412 F.3d 1319, 1323, 75 USPQ2d 1213, 1215 (Fed. Cir. 2005) (reference disclosing optional inclusion of a particular component teaches compositions that both do and do not contain that component); *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed.").

>See also MPEP § 2131.05 and § 2145, subsection X.D., which discuss prior art that teaches away from the claimed invention in the context of anticipation and obviousness, respectively.<

Art Unit: 1617

II. NONPREFERRED AND ALTERNATIVE EMBODIMENTS CONSTITUTE PRIOR ART

Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994) (The invention was directed to an epoxy impregnated fiber-reinforced printed circuit material. The applied prior art reference taught a printed circuit material similar to that of the claims but impregnated with polyester-imide resin instead of epoxy. The reference, however, disclosed that epoxy was known for this use, but that epoxy impregnated circuit boards have "relatively acceptable dimensional stability" and "some degree of flexibility," but are inferior to circuit boards impregnated with polyester-imide resins. The court upheld the rejection concluding that applicant's argument that the reference teaches away from using epoxy was insufficient to overcome the rejection since "Gurley asserted no discovery beyond what was known in the art." 27 F.3d at 554, 31 USPQ2d at 1132.). Furthermore, "[t]he prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed..". *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004).

In addition, Skovmand teaches a combination of at least one non-pyrethroid insecticide, specifically, pirimiphos-ethyl, in combination with at least one insect repellent, specifically, DEET, as instantly claimed.

Applicant further argues that evidence of the unexpected results of a composition combining pirimiphos-methyl (i.e., PM) and DEET are provided in PENNETIER et al. (Malaria Journal (2007) 6:38, p 1-7). In this research, Applicant argues that the authors (and inventors Cedric Pennetier and Jean-Marc Hougard) studied interactions between two repellents (DEET and KBR) and the organophosphate insecticide (PM). Applicant argues that the study assessed the residual efficacy and inhibition of blood feeding conferred by these mixtures against *Anopheles gambiae* mosquitoes (a malaria vector) and that the application rate of DEET/KBR was 10 g/m² and that for PM was 150 mg/m², these dosages being selected as the lower dosages

Art Unit: 1617

including 100% mortality in the tunnel assay (see, page 3, Treatment). Applicant argues that the research measured the lethal time (LT) and biting inhibition time (BIT). The lethal time corresponds to the mortality rate of mosquitoes whereas biting inhibition time is the blood feeding reduction assessed by comparing the proportion of blood-fed females in treated and control tunnels. Lethal time on mosquitoes (LT95 = 95% of killed mosquitoes) of the mixture DEET/PM persists for 87 days, whereas LT95 of PM alone is less than 6 days and LT95 of DEET alone is less than 3 days. Moreover, the time required to inhibit 95% of the blood feeding (BIT95) is 3 days for PM and 6 days for DEET, whereas BIT95 for the mixture DEET/PM is more than one month (37 days). In the second mixture concerning PM and KBR3023, LT95 of the mixture KBR3023/PM persists for 73 days, whereas LT95 of PM alone is less than 6 days and LT95 of KBR3023 alone is 3 days. Moreover, Applicant argues the BIT95 is 3 days for PM and 8 days for KBR3023, whereas BIT95 for the mixture KBR3023/PM is three weeks (21 days). Applicant argues that the difference of efficacy between expected and observed LT and BIT of DEET/PM or KBR3023/PM indicates a strong synergy between PM and DEET or PM and KBR3023 properties in terms of mortality and blood feeding inhibition and that this data clearly demonstrates the interest of a mixture of non-pyrethroid carbamate and organophosphate insecticides (such as PM) and a repellent of DEET or KBR3023. Accordingly, Applicant argues that the inventors of the present application have found a synergy between organophosphorous or carbamate insecticides and repellents such as DEET or KBR3023 and that the synergistic effect for fighting against pest and vector insects is new in regards of the literature and invention. Applicant points

Art Unit: 1617

out that this argument is supported by the recent publication of one mode of action of the repellent DEET, explaining this synergistic effect (CORBEL et al., BMC Biology (2009) 7:47) which means that the biological mechanisms underlying this synergistic effect are under investigation and cannot have been known or deduced from any prior publication (most particularly, KARL et al. and SKOVMAND) before the present invention. However, Applicant's arguments are not found persuasive because unexpected results have to be commensurate with the scope of the invention. "Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range. In re Clemens, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980)." The publications presented by Applicant discloses data that demonstrates synergy produced from mixtures of **one insecticide component, pirimiphos-methyl** ((i.e., O-[2-(dimethylamine)-6-methyl-4 pyrimidinyl] O, O-dimethyl phosphorothioate) in combination with and a repellent of DEET ((i.e., N, N-diethyl-met-toluamine) or KBR3023. However, claims 2 and 7 are not so limited as they disclose the whole class of carbamate and organophosphate insecticides. Objective evidence of nonobviousness, if any, must be commensurate in scope with that of the claimed subject matter. In re Kulling, 14 USPQ2d 1056 (Fed. Cir. 1990); In re Lindner, 173 USPQ 356 (CCPA 1972). Further, in the Restriction/ Election Response file on November 8, 2010, Applicant elected, without traverse, **pirimiphos-methyl** (i.e., O-[2-

Art Unit: 1617

(dimethylamine)-6-methyl-4 pyrimidinyl] O, O-dimethyl phosphorothioate) as the insecticide component and **DEET** (i.e., N, N-diethyl-meta-toluamine) as the insect repellent component. Therefore, the inclusion of KBR3023 (i.e., 2-(2- hydroxy-ethyl)-piperidine carboxylic acid ester of 1-methyl- propyl) as a repellent is broader than the elected species.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Courtney A. Brown whose telephone number is 571-270-3284. The examiner can normally be reached on 9:00 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun Sajjadi can be reached on 571-272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/588,492
Art Unit: 1617

Page 17

Courtney A. Brown
Patent Examiner
Technology Center 1600
Group Art Unit 1617

/Janet Epps-Smith/
Primary Examiner, Art Unit 1633